essure™

Permanent Birth Control System

Instructions For Use

IMPORTANT

? This product is intended to prevent pregnancy. It does not protect against HIV infection and other sexually transmitted diseases.

? Caution: Federal law restricts this device to sale by or on the order of a physician with appropriate training and experience.

? Do not attempt to use the **Essure** Permanent Birth Control System before completely reading and understanding the information contained in this Instructions for Use and the Physician Training Manual.

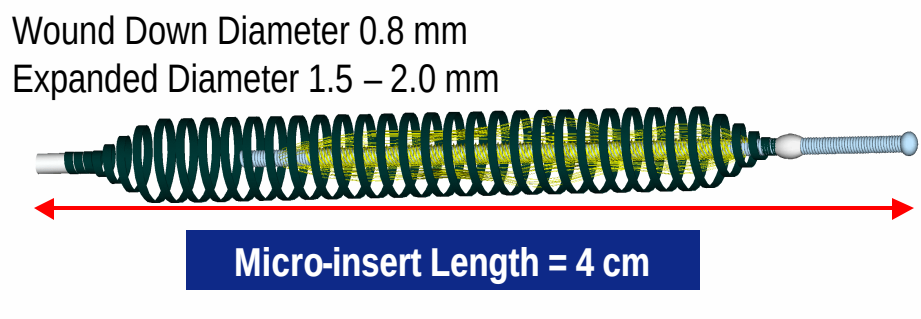
I. DEVICE DESCRIPTION

The **Essure Permanent Birth Control System** is designed to provide a non-incisional alternative to women seeking permanent contraception. Using a transcervical approach, one **Essure** Micro-insert is placed in the proximal section of each fallopian tube lumen. When the **Essure** Micro-insert expands upon release, it acutely anchors itself in the fallopian tube. Subsequently, the **Essure** Micro-insert elicits an intended benign occlusive tissue response, resulting in tissue in-growth into the device that permanently anchors the device and occludes the fallopian tube, resulting in permanent contraception.

The **Essure Permanent Birth Control System** is comprised of the **Essure** Micro-insert, a disposable delivery system, and a disposable Split Introducer.

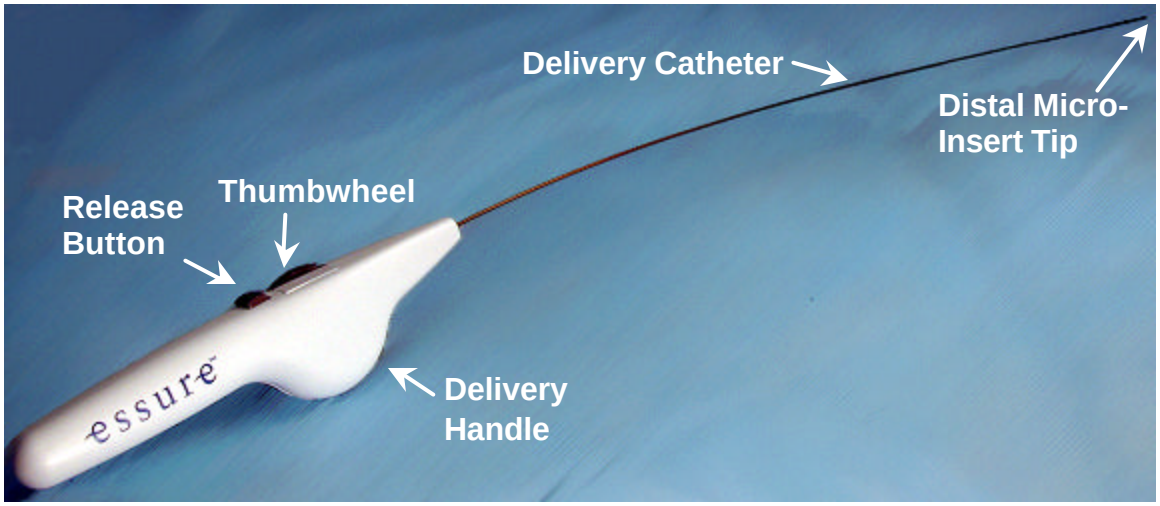
The **Essure** Micro-insert is a dynamically expanding Micro-coil that consists of a stainless steel inner coil, a Nickel Titanium (nitinol) expanding, superelastic outer coil, and polyethelene (PET) fibers. The PET fibers are wound in and around the inner coil. The Micro-insert, shown in **Figure 1** below, is 4 cm in length and 0.8mm in diameter in its wound down configuration. When released from the delivery system, the outer coil expands to 1.5 to 2.0 mm in diameter to anchor the Micro-insert in the varied diameters and shapes of the fallopian tube.

Figure 1
Essure Micro-insert (Shown in its Expanded Configuration)



The disposable delivery system, shown is **Figure 2** below, consists of a delivery wire, a release catheter, a delivery catheter and a delivery handle.

Figure 2
Essure Delivery System



NOTE: The delivery wire and the release catheter are not visible in the figure shown above.

The **Essure** Micro-insert is provided attached to the delivery wire, in a wound-down (low profile) configuration. The delivery wire is composed of a nitinol core wire, which is ground at the distal end to result in a flexible, tapered profile. The device is constrained by the release catheter which is sheathed by a flexible delivery catheter. A positioning bump on the tubing aids in proper placement of the device in the fallopian tube.

The delivery handle controls the device delivery and release mechanism. The thumbwheel on the delivery handle retracts both the delivery catheter and the release

catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to retracting the release catheter. The delivery wire is detached from the Micro-insert by rotating the system.

The Split Introducer is intended to help protect the **Essure** Micro-insert as it is being passed through the rubber port of the hysteroscope working channel.

II. INDICATIONS FOR USE

The **Essure System** is indicated for permanent birth control (female sterilization) by occlusion of the fallopian tubes.

III. CONTRAINDICATIONS

The **Essure Permanent Birth Control System** should not be used in any patient who is:

- Uncertain about her desire to end fertility.
- Currently taking systemic corticosteroids.

Or any patient with any of the following conditions:

- Pregnancy or suspected pregnancy.
- Delivery or termination of a second trimester pregnancy less than 6 weeks before **Essure** Micro-insert placement.
- Active or recent pelvic infection.
- Untreated acute cervicitis.
- Gynecological malignancy (suspected or known).
- Known abnormal uterine cavity or fallopian tubes that would make visualization of the tubal ostia and/or cannulation of the proximal fallopian tube difficult or impossible.
- Known allergy to contrast media.
- Known hypersensitivity to nickel confirmed by skin test.

IV. WARNINGS

- Whenever possible, Micro-insert placement should be performed during days 7-14 of the menstrual cycle (where day 1 represents the first day of bleeding) in order to (a) decrease the potential for Micro-insert placement in a patient with an undiagnosed (luteal phase) pregnancy and (b) enhance visualization of the fallopian tube ostia.
- In order to reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
- When introducing the **Essure** Micro-insert into the fallopian tube, never advance the Micro-insert(s) against excessive resistance.
- If tubal or uterine perforation occurs or is suspected, immediately discontinue the **Essure** placement procedure.
- Do not continue to advance the **Essure** System once the positioning bump on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory Micro-insert placement and/or tubal/uterine perforation.
- Once the Micro-insert has been placed, Micro-insert removal should not be attempted hysteroscopically, unless 18 or more coils of the **Essure** Micro-insert are trailing into

the uterine cavity. Removal of such a Micro-insert should be attempted immediately following the placement; however, removal may not be possible.

- The patient cannot rely on the **Essure** Micro-inserts for contraception and must use alternative contraception until an x-ray performed three months post-Micro-insert placement demonstrates satisfactory Micro-insert location.
- Following placement of the **Essure** Micro-inserts, it is recommended that electrocautery be avoided in surgical procedures undertaken on the uterine cornua and fallopian tubes. In other procedures in the pelvis, avoid the use of electrocautery within 4 cm of the Micro-insert. Due to the presence of the **Essure** Micro-inserts, there may be risks associated with such procedures that, at this time, have not been identified.
- Any intrauterine procedure performed following the **Essure** procedure could interrupt the ability of the **Essure** Micro-inserts to prevent pregnancy. In addition, the presence of the **Essure** Micro-inserts could involve risks associated with such procedures that, at this time, have not been identified.
- There are no data on the safety or effectiveness of surgery to reverse the **Essure** procedure.
- Patients may decide, in future years, to undergo *in vitro* fertilization (IVF) to become pregnant. The effects of the **Essure** Micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the Micro-insert to the patient, to the fetus and to the continuation of a pregnancy are also unknown.
- Do not use the **Essure** System if the sterile package is open or damaged. Do not use if the Micro-insert is damaged.

V. PRECAUTIONS

- Testing to ensure safety and compatibility with Magnetic Resonance Imaging (MRI) has been conducted using a 1.5 Tesla magnet. The **Essure** Micro-inserts were found to be MR safe at this field strength. However, the presence of the Micro-inserts produces an MR artifact which will obscure imaging of local tissue.
- Unusual uterine anatomy may make it difficult to place the **Essure** Micro-inserts.
- If **Essure** Micro-insert placement attempts are not successful after 10 minutes of attempted cannulation per tube, the case should be terminated and potentially rescheduled.
- Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** Micro-insert placement. No attempt should be made to place a Micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is accessible and patent.
- Do not advance the **Essure** System if the patient is experiencing extraordinary pain or discomfort.
- For single use only. Never attempt to resterilize an **Essure** Micro-insert or delivery system.
- When removing the metal obturator from the introducer, there is a possibility that saline will be washed back through the operating channel of the hysteroscope. Proper eye and face protection should be utilized.
- The Split Introducer must be used in order to avoid damage to the device tip.

? The Split Introducer should be removed after the Micro-insert is introduced into the working channel. The working channel stopcock must remain in the open position to avoid damage to the Micro-insert or to the introducer.

VI. ADVERSE EVENTS

A. Patient Population

A total of 677 women (implanted with a total of 1,341 devices) who participated in two separate clinical investigations to evaluate the safety and effectiveness of the **Essure Permanent Birth Control System** provides the basis of the observed adverse event rates presented in this section. The total device exposure for this patient population is equivalent to over 1000 patient years.

B. Patient Deaths

No (zero) patient deaths were observed in this patient population.

C. Observed Adverse Events

The following adverse events were reported with the **Essure** Micro-insert: expulsion (2.2%), perforation (1.5%), other unsatisfactory device location (0.6%).

Other adverse events or side effects reported as a result of the hysteroscopic placement procedure included:

Cramping (20%), nausea and vomiting (8%), dizziness or lightheadedness (5%), vasovagal response (1%), hypervolemia (0.2.%), and proximal band detachment (0.6%). In addition, the majority of women experienced mild to moderate pain during and immediately following the procedure, and the majority of women experienced spotting for an average of 3 days.

Table 1 summarizes all adverse events rated by the Investigators to be at least "possibly" related to the **Essure** Micro-insert or Micro-insert placement procedure during the first year of reliance on **Essure** in the Pivotal trial (approximately 15 months post-device placement and during the first 12 months post-device placement in the Phase II trial).

Table 1
Adverse Events by Body Systems, First Year*
(N=677 patients implanted with at least one device)

Adverse Events by Body System	Number	Percent
Abdominal:		
Abdominal pain/abdominal cramps	16	3.4%
Gas/bloating	6	1.3%
Musculo-skeletal:		
Back Pain/low Back Pain	40	8.4%
Arm/leg Pain	4	0.8%
Nervous/Psychiatric:		
Headache	12	2.5%
Premenstrual Syndrome	3	0.6%
Genitourinary:		
Dysmenorrhea/menstrual cramps (severe)	11	2.3%
Pelvic/lower abdominal pain (severe)	12	2.5%
Persistent increase in menstrual flow	9**	1.9%
Vaginal discharge/vaginal infection	7	1.5%
Abnormal bleeding - timing not specified (severe)	5	1.1%
Menorrhagia/prolonged menses (severe)	5	1.1%
Dyspareunia	14	2.9%
Pain/discomfort - uncharacterized:	14	2.9%

* Only events occurring in $\geq$ 0.5% are reported
** Eight women reported persistent *decrease* in menstrual flow

D. Potential Adverse Events Not Observed in Clinical Studies

The following adverse events were not experienced by women who participated in clinical studies evaluating the **Essure Permanent Birth Control System** but are still possible:

- Pregnancy and ectopic pregnancy in women relying on Essure[1]
- Perforation (a small hole) in internal bodily structures other than the uterus and fallopian tube.
- Potential for adnexal infection/salpingitis.
- Risks associated with the hysterosalpingogram or X-rays.
- The effect of future medical procedures that involve the uterus or fallopian tubes on the ability of the **Essure** Micro-insert to provide protection against pregnancy.
- Risks associated with surgery to reverse the **Essure** procedure.

There is the potential that unknown risks exist.

[1] One women in the Phase II study who received a prior device design that was discontinued in 1998 (the Beta design of the STOP device) became pregnant after nearly two years of reliance. That pregnancy is not included in the effectiveness rate calculations, since that device design was not subject of the PMA that supported approval of the **Essure** Permanent Birth Control System.

E. Adverse Event Reporting

Any adverse event (clinical incident) involving the **Essure Permanent Birth Control System** should be reported to Conceptus immediately.
To report an incident, call (800) XXX-XXXX.

VII. CLINICAL STUDIES

Conceptus has conducted two clinical trials (a Phase II Trial and a Pivotal Trial) to demonstrate the safety and effectiveness of the **Essure Permanent Birth Control System** in providing permanent contraception. Results of these trials were reported in the premarket approval application (PMA) that supported market approval for the **Essure** product. Details of these clinical trials are presented below.

A. Purpose of the Study, Study Design, Primary Endpoints

The purpose of both studies was to evaluate the safety and effectiveness of the **Essure Permanent Birth Control System** in providing permanent contraception.

The Phase II study was a prospective, multi-center, international study of women seeking permanent contraception. The objectives of the study were to evaluate:

- The woman's tolerance of, and recovery from, the Micro-insert placement procedure;
- The safety of the Micro-insert placement procedure;
- The woman's tolerance of the implanted Micro-inserts;
- The long-term safety and stability of the implanted Micro-inserts; and
- The effectiveness of the Micro-inserts in preventing pregnancy.

The Pivotal study was a prospective, multi-center international study of women seeking permanent contraception. The study used findings from the U.S. Collaborative Review of Sterilization (CREST[1] study) as a qualitative benchmark. The primary endpoints for the study included:

- Prevention of pregnancy;
- Safety of device placement procedure, and;
- Safety of device wearing.

The secondary endpoints for the study included:

- Participant satisfaction with device placement procedure;
- Participant satisfaction with device wearing;
- Bilateral device placement rate, and;
- Development of a profile for an appropriate candidate for the Essure procedure.

B. Patients Studied

The study population of the two studies combined consisted of 664 women in whom bilateral device placement was achieved. All study participants were between 21 and 45 years of age and were seeking permanent contraception prior

to enrollment in the study. Additionally, all women had at least one live birth, had regular, cyclical menses and were able and willing to use alternative contraception for the first three months following **Essure** device placement.

C. Methods

All study participants were screened for eligibility to participate in the clinical study. A complete medical history was obtained. A physical examination, a pelvic examination and required laboratory tests (including a pregnancy test) were conducted.

An **Essure** device placement procedure was attempted on each fallopian tube. In the Pivotal Trial, a pelvic x-ray was performed within 24 hours following device placement to serve as a baseline evaluation of device location. Participants were instructed to use either a barrier contraceptive method or oral contraceptives for the first 3 months following the device placement procedure.

A hysterosalpingogram (HSG) was performed three months post device placement to evaluate device location and fallopian tube occlusion. If both fallopian tubes were occluded and both devices were satisfactorily placed within the fallopian tubes, the participant was instructed to discontinue use of alternative contraception and use only the **Essure** devices for prevention of pregnancy.

D. Results

Of the 643 women enrolled in the clinical trials (with bilateral Micro-insert placement) and who relied on the **Essure Permanent Birth Control System** for contraception, no (zero) pregnancies were reported[2]. Adverse events that were reported in the clinical study are provided in Section VI., C above, and events by study are provided below.

Table 2 presents the principal safety and effectiveness results.

[2] One women in the Phase II study who received a prior device design that was discontinued in 1998 (the Beta design of the STOP device) became pregnant after nearly two years of reliance. That pregnancy is not included in the effectiveness rate calculations, since that device design was not subject of the PMA that supported approval of the **Essure** Permanent Birth Control System.

Table 2
Principal Safety and Effectiveness Results

Outcome	Phase II N=227		Pivotal N=507	
	Number	**Percent**	**Number**	**Percent**
Bilateral Placement	200/227	88%	464/507	92%
Reliance Rate (among bilateral placements)	194/200	97%	449/464	97%
One-year Effectiveness Rate	-	99.5%	-	99.8%*
Two-year Effectiveness Rate	-	99.4%	-	-

*** The actual observed effectiveness rate in both of these trials was 100% as of the date when the PMA was submitted to the FDA. The 99.8% effectiveness rate shown in this table is a statistical estimate of the effectivenesss for future procedures.**

Table 3 provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

Table 3
Pregnancy Rates for Birth Control Methods
(For One Year of Use)

"Typical Use" rates mean that the method either was *not always used correctly* or was *not used with every act of sexual intercourse* (e.g., sometimes forgot to take birth control pill as directed and became pregnant), or was *used correctly* but *failed anyway*.

"Lowest Expected" rates mean that the method was *always used correctly* with *every act of sexual intercourse but failed anyway* (e.g., always took a birth control pill as directed but still became pregnant).

Method	Typical Use Rate of Pregnancy	Lowest Expected Rate of Pregnancy
Sterilization:		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
Hormonal Methods:		
Implant *(Norplant ™ and Norplant ™ 2)*	0.05%	0.05%
Hormone Shot *(Depo-Provera™)*	0.3%	0.3%
Combined Pill *(Estrogen/Progestin)*	5%	0.1%
Minipill *(Progestin only)*	5%	0.5%
Intrauterine Devices (IUDs):		
Copper T	0.8%	0.6%
Progesterone T	2%	1.5%
Barrier Methods:		
Male Latex Condom[1]	14%	3%
Diaphragm[2]	20%	6%
Vaginal Sponge *(no previous births)*[3]	20%	9%
Vaginal Sponge *(previous births)*[3]	40%	20%
Cervical Cap *(no previous births)*[2]	20%	9%
Cervical Cap *(previous births)*[2]	40%	26%
Female Condom	21%	5%
Spermicide: *(gel, foam, suppository, film)*	26%	6%
Natural Methods:		
Withdrawal	19%	4%
Natural Family Planning *(calendar, temperature, cervical mucus)*	25%	1-9%
No Method:	85%	85%

[1] Used Without Spermacide [2] Used With Spermacide [3] Contains Spermacide

Data adapted from: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J. Stewart F, et al Contraceptive Technology: Seventeenth Revised Edition. New York. NY: Ardent Media, 1998.

VIII. INDIVIDUALIZATION OF TREATMENT

The **Essure Permanent Birth Control System** is available in one size only. The risks and benefits previously described in Section VII - CLINICAL STUDIES should be carefully considered for each patient before use of the **Essure Permanent Birth Control System**. Patient selection factors to be assessed should include:

- Patient's certainty about her desire to end fertility,
- Gynecological co-morbidities (e.g., pelvic infection, cervicitis, vaginal bleeding), and
- Patient's morphologic suitability for transcervical delivery/placement of Micro-inserts.

The final treatment decision is at the discretion of the patient.

A. Use in Specific Populations

The safety and effectiveness of the **Essure Permanent Birth Control System** has not been established in patients with any of the following characteristics:

- Patients less than 21years old or greater than 45 years old
- Patients who delivered a baby or terminated a second trimester pregnancy less than 6 weeks before **Essure** Micro-insert placement.

IX. PATIENT COUNSELING INFORMATION

IMPORTANT: Patients should be counseled that this product is intended to prevent pregnancy. It does not protect against HIV infection and other sexually transmitted diseases.

The physician should consider the following points when counseling the patient about this device:

- Details contained in the Patient Information Booklet regarding risks associated with placement of the **Essure** Micro-inserts.
- The procedure is permanent, and there are no data on the safety and effectiveness of a reversal procedure.
- There is a mandatory waiting period of at least 3 months after the procedure before the doctor can advise the patient whether the **Essure** Micro-insert can be relied upon for permanent birth control.
- Like all methods of birth control, the **Essure** procedure should not be considered 100% effective.

Conceptus recommends that the physician disclose to the patient (in written form) all risks associated with treatment using the **Essure Permanent Birth Control System,** that the **Essure** procedure is permanent, and that there are no data on the safety or effectiveness of a reversal procedure. Please also refer to the Patient Counseling section of the Technical Bulletin from the American College of Obstetricians and Gynecologists (ACOG) regarding female sterilization.

X. HOW SUPPLIED

CONTENTS: Two (2) Essure Permanent Birth Control Systems
One (1) Instructions for Use
One (1) Temporary Patient Identification Card

STERILE: Each **Essure Permanent Birth Control System** is sterilized using ethylene oxide and is supplied sterile for single use only. Do not reuse or resterilize. Resterilization may adversely affect proper mechanical function and could result in patient injury. Carefully inspect the sterile package for damage or defects prior to use.

STORAGE: Store in a cool, dry place.

XI. PHYSICIAN TRAINING MANUAL

The **Essure Permanent Birth Control System** Physician Training Manual contains detailed information not included in this Instructions for Use. Refer to the Physician Training Manual for additional information as required.

XII. DIRECTIONS FOR USE

A. Prior to Micro-insert Placement Procedure

1. Micro-insert placement should be performed during days 7-14 of the menstrual cycle (where day 1 represents the first day of bleeding) in order to (a) decrease the potential for Micro-insert placement in a patient with an undiagnosed pregnancy and (b) enhance visualization of the fallopian tube ostia.

2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to or immediately preceding the Micro-insert placement procedure.

3. Administration of a non-steroidal anti-inflammatory drug (NSAID) such as diclofenac (Cataflam/Voltaren) or ketorolac (orally or via I.M. injection) is recommended one to two hours before the Micro-insert placement procedure. If using only a paracervical block, diazepam (PO), or a similar agent, may also be offered 30 minutes prior to the procedure to reduce anxiety.

B. Micro-insert Placement Procedure

The **Essure** Micro-insert placement procedure can be performed in an outpatient or office surgery setting. Sterile technique should be used during the Micro-insert placement procedure following universal precautions. The amount of time required to complete the Micro-insert placement procedure should not exceed 30 minutes.

1. Place the patient in the lithotomy position.

2. Introduce a speculum into the vagina to allow access to the cervix. Prep the cervix with betadine or other suitable antibacterial solution according to standard practice.

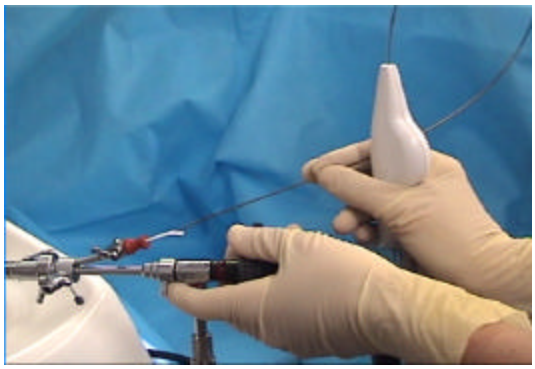
3. Local anesthesia is the preferred method for implantation of the Micro-inserts. A paracervical block may be administered. Midazolam (IV), or a similar agent, may also be administered to prevent or reduce discomfort if needed.

4. Insert a sterile hysteroscope, with attached camera and operating channel (? 5 French), through the cervix into the uterine cavity. Do not perform cervical dilation unless necessary to allow hysteroscope insertion. In order to prevent uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.

5. Uterine cavity distention should be accomplished with a physiologic saline infusion through the inflow channel of the hysteroscope. It is strongly recommended that the saline solution be pre-warmed to body temperature and introduced under gravity feed to minimize spasm of the fallopian tubes. Adequate uterine distention must be achieved and maintained throughout the procedure in order to allow identification of and access to the fallopian tube ostia. Standard fluid monitoring procedures should be followed throughout the procedure.

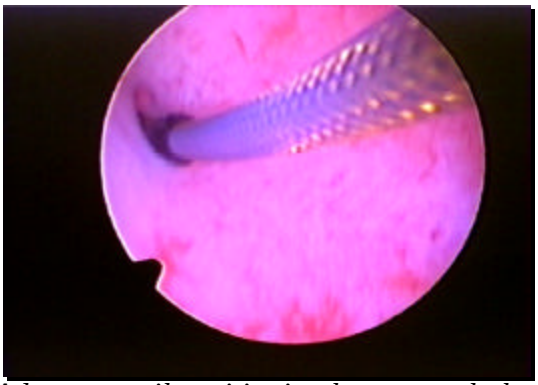
6. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** Micro-insert placement. No attempt should be made to place a Micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is patent.

7. Once the fallopian tube ostia have been identified, insert the Split Introducer through the rubber port on the hysteroscope working channel. The operating channel stopcock should remain in the open position (the device and/or introducer can be damaged if the stopcock closes on either device). Place the **Essure** delivery system through the introducer and advance through the operating channel of the hysteroscope.



*Insert Split Introducer and **Essure** Micro-insert through rubber port on hysteroscope working channel*

8. Advance the **Essure** delivery system into the proximal fallopian tube with slow, steady forward movement to prevent tubal spasm. Advance the delivery system until the positioning bump on the delivery catheter reaches the fallopian tube ostium. This visual marker indicates that the **Essure** Micro-insert is spanning the intramural and the proximal isthmic segments of the fallopian tube, with the outer coil spanning the uterotubal junction. This is the ideal placement for the **Essure** Micro-insert.



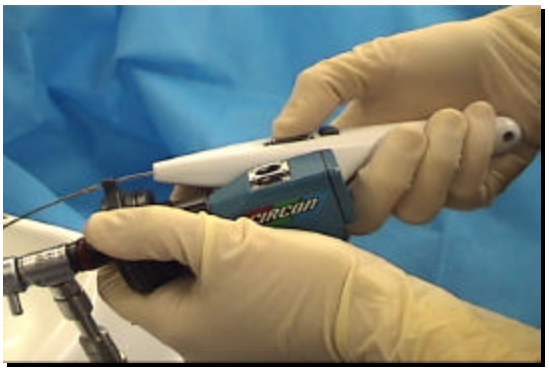
Advance until positioning bump at tubal ostium. This is visual indicator for proper position for deployment.

9. Proper concentric alignment of the delivery catheter with the tubal lumen is suggested by the ability to advance the catheter under direct visualization without undue resistance. Resistance to advancement is usually apparent if: 1) the black marker on the outside surface of the catheter is seen not to advance forward towards the tubal ostium, and/or 2) the delivery catheter bends or flexes excessively, thus preventing the physician from applying forward pressure on the catheter assembly. When such resistance to forward advancement of the catheter is observed, no further attempts should be made to place the Micro-insert in order to avoid the possibility of uterine perforation or inadvertently placing the Micro-insert in the uterine musculature rather than

within the tubal lumen. A follow-up HSG should be undertaken to determine tubal patency.

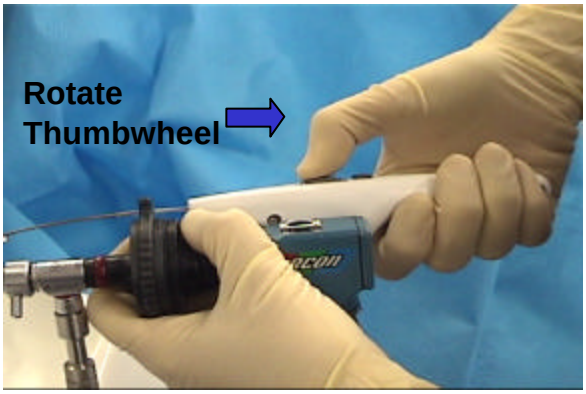
10. If it is not possible to advance the catheter to the positioning bump after several minutes, a perfusion test with a patency catheter may be employed, if it has not already been utilized, to determine tubal patency. If the tube is blocked or the catheter cannot be advanced to the positioning bump, the case should be terminated. If Micro-insert placement is not successful after 10 minutes of attempted cannulation per tube, the case should be terminated.

11. Only after the delivery catheter has been advanced to the positioning bump should the Micro-insert be deployed. To do so, first stabilize the handle of the **Essure** Micro-insert against the hysteroscope or camera to prevent inadvertent forward movement of the **Essure** System during retraction of the delivery catheter.



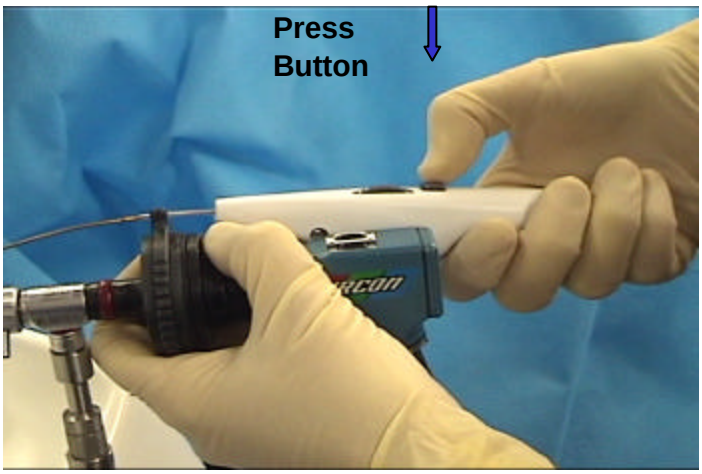
*Stabilize Handle Against Camera Head or Some Other Fixed Object to Prevent Inadvertent Forward Movement of the **Essure** System*

12. Being certain that the positioning bump is at the fallopian tube ostium, rotate the thumb-wheel on the handle towards the operator. This should be accomplished no faster than 1 click per second until the wheel no longer rotates. This facilitates withdrawal of the delivery catheter. The black positioning bump will be seen to move away from the tubal ostium (towards the hysteroscope) and disappear into the operating channel. Withdrawal of the delivery catheter exposes the wound-down **Essure** Micro-insert attached to the release catheter. Approximately 1cm of the Micro-insert (wound-down coils) should appear trailing into the uterus when the delivery catheter is withdrawn. If more is visible, the Micro-insert should be repositioned, if possible, before proceeding to step #13.



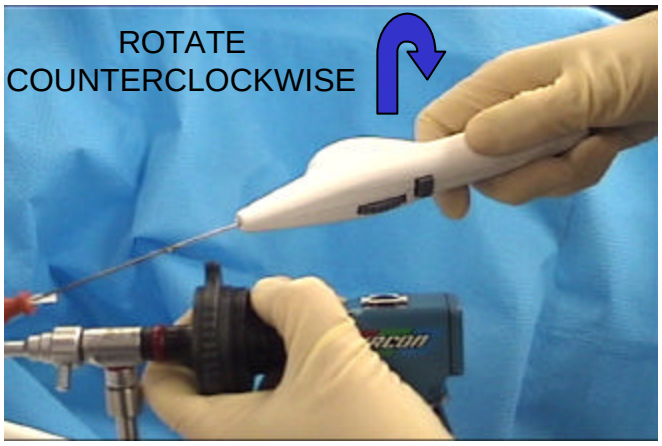
Rotate Thumbwheel to Retract Catheter

13. After retracting the delivery catheter, depress the button on the handle to enable the thumb-wheel to be further rotated. Rotate the thumb-wheel towards the operator to withdraw the release catheter. When the thumb-wheel cannot be rotated any further, release catheter withdrawal is complete. Withdrawal of the release catheter enables the outer coil of the **Essure** Micro-insert to expand. The operator should see the outer coils expand. If expansion is not observed, gently move the delivery wire away from the uterine wall to release pressure on the outer coil.



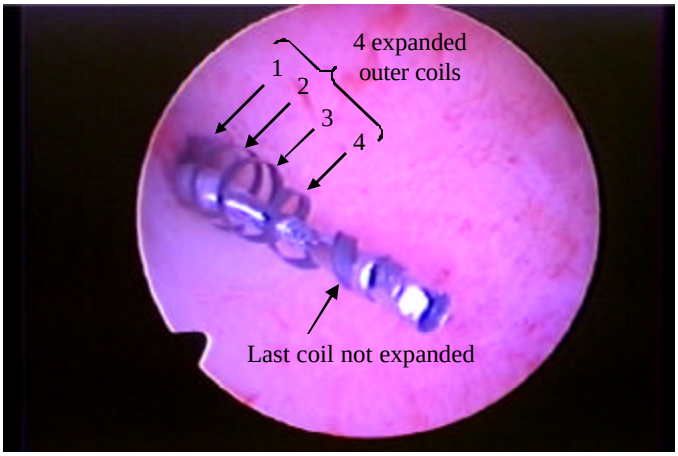
After Complete Retraction of Catheter,
Press Button to Enable Thumbwheel to Rotate Again

14. **Wait approximately 10 seconds to allow the outer coils to fully expand.** Once the outer coils are expanded, rotate the entire handle counter-clockwise at least 10 rotations. Continue to rotate while gently pulling backwards on the handle to release the delivery wire from the **Essure** Micro-insert. The delivery system will then be withdrawn through the working channel of the hysteroscope.



Rotate Handle Counter-Clockwise to Detach Delivery Wire from Micro-insert

15. Once the delivery system has been withdrawn, the position of the **Essure** Micro-insert should be assessed. There should ideally be 3 to 8 expanded outer coils of the **Essure** Micro-insert trailing into the uterus.



*Expanded Outer Coils of the **Essure** Micro-insert Trailing Into the Uterus Indicates Ideal Placement*

16. Unless the Micro-insert has a trailing length that is greater than 18 expanded outer coils, the Micro-insert should be left in place and evaluated via pelvic x-ray three months post device placement.

WARNING: Micro-insert removal should not be attempted hysteroscopically once the Micro-insert has been placed, unless 18 or more coils of the Essure Micro-insert are trailing into the uterine cavity. Attempted removal of a Micro-insert having less than 18 or more coils trailing into the uterine cavity may result in fallopian tube perforation or other patient injury.

IMPORTANT: If the Micro-insert was inadvertently deployed in the uterine cavity and not into the tube, then the Micro-insert should be removed from the uterus and another attempt made at Micro-insert placement in the tube.

17. If there are 18 or more expanded outer coils are trailing into the uterus, then the Micro-insert should be immediately removed from the uterus (as described in steps 1-5) and another attempt made at Micro-insert placement in the tube. **Micro-insert removal may not always be possible.**

    1 - As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.

    2 - Introduce a grasping instrument through the hysteroscope working channel.

    3 - Grasp the outer coil of the **Essure** Micro-insert. Try to grasp the outer and inner coil of the Micro-insert together.

    4 - Slowly pull back on the grasping instrument and withdraw the hysteroscope at the same time, so that the entire system is removed from the uterus.

    5 - The outer coil and/or the inner coil of the **Essure** Micro-insert may stretch or elongate as Micro-insert removal is being attempted.

    If complete Micro-insert removal is accomplished, an attempt should be made to place another **Essure** Micro-insert. If the physician is not completely satisfied that the entire **Essure** Micro-insert has been removed from the fallopian tube, another Micro-insert should **NOT** be placed in that tube and a post-placement x-ray should be taken to determine if a Micro-insert fragment remains *in vivo.*

18. Record the length of the Micro-insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concern regarding potential perforation. These should be noted in patient records for subsequent reference when reviewing the 3-month x-ray (See Section C below). Additionally, the following information should be noted in the patient records:

- ? Concern, at the time of device placement, of possible perforation due to excessive force required on the delivery catheter, a sudden loss of resistance, or a trailing length of less than 0 mm, as seen hysteroscopically after device placement.
- ? The visible trailing length of the micro insert at the conclusion of device placement if less than 3 mm or greater than 10 mm.
- ? Identification of the tubal ostium, at the device placement procedure, was compromised due to poor distention, poor illumination or poor visualization, secondary to endometrial debris.

19. Repeat the **Essure** Micro-insert placement procedure in the contralateral fallopian tube.

C. Patient Follow-up Requirements

Patients should be scheduled for a pelvic x-ray, 3 months following the **Essure** micro insert placement procedure for the purpose of evaluating Micro-insert retention and location. Ideally, the x-ray should be performed at a time so as to allow the physician appropriate time to evaluate the x-ray and discuss the findings with the patient. Precise and correct evaluation of the pelvic x-ray is critical to the physician's decision as to whether or not it is appropriate for his or her patient to discontinue alternative contraception.

X-rays will be interpreted as either satisfactory, suspicious, or unsatisfactory.

A satisfactory x-ray is one in which the micro inserts appear to be in the tubal lumen and spanning the uteral tubal junction and appear relatively symmetrical. Patients whose x-rays are determined to be satisfactory, may be told to rely on the Essure micro insert for contraception and to discontinue alternative contraception.

An x-ray that is deemed to be suspicious is one in which one or both of the Micro-inserts appear to be distal, or proximal, to what would be an ideal position in the fallopian tube. Alternatively, a suspicious x-ray may be one in which one or more of the devices appear to have completely perforated the uterine tube and myometrium, so as to appear relatively asymmetrical. Patients whose x-rays are determined to be suspicious should be instructed to continue alternative contraception, and to undergo an HSG so as to evaluate tubal patency.

An x-ray that is deemed to be unsatisfactory is one in which there is obvious intra-peritoneal location of one or more Micro-inserts, or where there is clear evidence of expulsion of one or more of the Micro-inserts. Patients whose x-rays are deemed to be unsatisfactory, should be instructed to continue alternative contraception. Patients who wish to be considered for re-attempt at placement of the **Essure** device, should undergo an HSG, so as to evaluate tubal patency and then be managed according to the instructions in the Physician Training Manual for management of patients with unsatisfactory Micro-insert location.

The following issues (related to the device placement procedure, and patient symptoms for the 3-months since device placement), should be considered in interpreting the pelvic x-rays. These include:

1. Concern, at the time of device placement, of possible perforation due to excessive force required on the delivery catheter, a sudden loss of resistance, or a trailing length of less than 0 mm, as seen hysteroscopically after device placement.

2. The visible trailing length of the micro insert at the conclusion of device placement is either less than 3 mm or greater than 10 mm.

3. Identification of the tubal ostium, at the device placement procedure, was compromised due to poor distention, poor illumination or poor visualization, secondary to endometrial debris. Such situations might not only affect the ability to correctly place the micro inserts, but might also adversely affect the ability to evaluate the trailing length of the device.

4. The patient has complained of consistent uterine cramping, and/or bleeding/spotting since the performance of the procedure.

ALL PATIENTS WITH SUSPICIOUS OR UNSATISFACTORY X-RAYS MUST BE ADVISED TO CONTINUE ALTERNATIVE CONTRACEPTION, UNTIL PERFORMANCE OF HSG TO EVALUATE EVIDENCE OF TUBAL PATENCY OR OCCLUSION.

D. Micro-insert Removal

Once the Micro-insert placement procedure is concluded, Micro-insert removal should only be attempted if a patient is experiencing an adverse event(s) related to the Micro-insert or if she demands Micro-insert removal. Such removal should not be attempted hysteroscopically and will likely require a cornual resection if the Micro-insert is across the utero-tubal junction.

IMPORTANT: Hysteroscopic attempts to remove the Micro-insert should only be performed during the Micro-insert placement procedure.

Detailed recommendations for Micro-insert removal are contained in the Physician Training Manual.

XIII. PATIENT'S MANUAL

The Patient Information Booklet entitled "A New Method of Permanent Birth Control: The Essure™ Permanent Birth Control System" contains valuable information for patients considering treatment with the **Essure Permanent Birth Control System**. Please be sure to provide a copy of this brochure to all patients considering treatment with the **Essure Permanent Birth Control System**.

XIV. REFERENCES

1. Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996: 174:1161-1170.

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